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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/764,375 | 01/23/2004 | Arnold Stan Lippa | 10596-016-999 | 9972 |
| 20583 | 7590 | 09/21/2004 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | SOLOLA, TAOFIQ A | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1626 | | |

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/764,375 | LIPPA ET AL. | |
| | Examiner Taofiq A. Solola | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 53-56 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 53-56 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claims 53-56 are pending in this application.

Claims 1-52 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 21, lines 4-5, the specification discloses hexane:isopropyl (95:5) and diethylamine (0.05 %) as the eluent. There is no disclosure that any and/all organics is applicable as eluent in the instant process. The eluent is a critical element of the invention and must be fully disclosed. Therefore, the specification lacks adequate support for claims 53-56. Applicant must show possession of the invention by describing it with all the claimed limitations.

Lookwood v. American Airlines Inc. 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By limiting the eluent to hexane: isopropyl (95:5) and diethylamine (0.05 %) the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 53-56, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "eluent", line 3, claim 53 and line 3, claim 55, is a critical element of the invention and must be fully disclosed. Therefore, claims 53-56 are indefinite. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). By limiting the eluent to hexane: isopropyl (95:5) and diethylamine (0.05 %) the rejection would be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. *J. Chrom. A*, (1999) Vol. 865, pages 211-226.

Applicant claims a process for separating racemic mixture of -1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane with chiral polysaccharide stationary phase and an organic eluent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Miller et al., teach a process for separating racemic mixture with chiral polysaccharide stationary phase and polar organic solvents a eluent.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Miller et al., is that applicant separates racemic mixture of $-1-(3,4\text{-dichlorophenyl})-3\text{-azabicyclo}[3.1.0]\text{hexane}$ instead of "racemates" by Miller et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, Miller et al., teach that polar organic solvents with polysaccharide stationary phase are useful for separating racemic mixtures, and the term racemates embraces the racemate mixture of $-1-(3,4\text{-dichlorophenyl})-3\text{-azabicyclo}[3.1.0]\text{hexane}$. Miller et al., also teach advantages of using the process to separate racemates. See the abstract, introduction, materials and conclusion.

Therefore, the instant invention is prima facie obvious from the teaching of Miller et al. One of ordinary skill in the art would have known to separate racemate mixture of $-1-(3,4\text{-dichlorophenyl})-3\text{-azabicyclo}[3.1.0]\text{hexane}$ with polar organic solvents and polysaccharide stationary phase at the time the invention was made. The motivation is from the teaching of Miller et al., that polar organic solvents with polysaccharide stationary phase are useful for separating racemic mixtures and the advantages thereof.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Art Unit: 1626

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TAOIQ SOLOLA
PRIMARY EXAMINER
Group 1626

September 17, 2004